

Appl. No. : 10/553,376  
Filed : October 19, 2005

## REMARKS

Claim 1 has been amended. New claims 9 and 10 are added. Claims 1-10 are now pending in this application. Claims 6-8 are withdrawn from consideration as directed to a non-elected invention. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

### Rejection under 35 U.S.C. § 102(b) (Colpan)

Claims 1-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Colpan, et al.

It is well established that in order to anticipate a claim, the reference must teach every element of the claim (M.P.E.P. 2131).

Claim 1 has been amended to recite “heating the obtained solution at 80 to 100°C”. New claims 9 and 10 recite “heating … performed at 90 to 100°C” and “heating … performed at 90 to 100°C”, respectively. Support for the amendment is found in the specification at page 6, lines 17-18. This limitation is not taught by Colpan, et al.

Colpan, et al. teach that “a protease is added, and the mixture is incubated for 10 min. at 70° C. or for a longer period of time at lower temperatures (e.g. for 30 min. at room temperature)” (col. 9, lines 18-20). Colpan, et al. do not teach “heating the obtained solution at 80 to 100°C” as now claimed. Accordingly, Colpan, et al do not anticipate the presently claimed invention.

As taught by Applicants’ specification, heating the sample at “80 to 100°C” provides the advantage that PCR inhibitory substances such as proteins are denatured. These PCR inhibitory substances are then removed from nucleic acids by gel filtration (see present specification, page 6, last paragraph). The claimed method is simpler and may be performed more quickly than present methods. As taught in the Examples of the specification, the isolation may be done in 10 minutes (page 10, line 7) while existing methods require 20-25 minutes (page 9, lines 10 and 24).

In view of Applicants’ amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

### Rejection under 35 U.S.C. § 102(b) (Shigenaga, et al.)

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Claims 1-4 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Shigenaga, et al. (Methods in Enzymology (1994) 234: 16-33).

This rejection is believed to be overcome on the same basis as the rejection above over Colpan, et al. That is, Claim 1 has been amended to recite "heating the obtained solution at 80 to 100°C". New claims 9 and 10 recite "heating ... performed at 90 to 100°C" and "heating ... performed at 90 to 100°C", respectively. Support for the amendment is found in the specification at page 6, lines 17-18.

Shigenaga, et al do not teach this limitation. Shigenaga, et al. teach protein digestion for 1 hour at 50°C in the presence of proteinase K or pronase (pages 18-19, bridging paragraph). DNA is then isolated by phenol extraction. After enzymatic digestion, the DNA is separated by chromatographic procedures as described on page 21.

In contrast, by Applicants' method, the sample solution is heated to 80-100°C to denature the proteins. The heated solution is then subjected to gel filtration, thereby removing the protein contaminants. Such method is not taught by Shigenaga, et al. Specifically, Shigenaga, et al. do not teach heating of the sample at any time to 80-100°C. Accordingly, Shigenaga, et al. do not anticipate the presently claimed invention.

As taught by Applicants' specification, heating the sample at "80 to 100°C" provides the advantage that PCR inhibitory substances such as proteins are denatured. These PCR inhibitory substances are then removed from nucleic acids by gel filtration (see present specification, page 6, last paragraph). The claimed method is simpler and may be performed more quickly than present methods. As taught in the Examples of the specification, the isolation may be done in 10 minutes (page 10, line 7) while existing methods require 20-25 minutes (page 9, lines 10 and 24).

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

### **CONCLUSION**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: Che S. Chereskin  
Che Swyden Chereskin, Ph.D.  
Registration No. 41,466  
Agent of Record  
Customer No. 20,995  
(949) 721-6385

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070207